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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,783	10/02/2000	William J. McBride	018733/0997	1348

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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/676,783

Applicant(s)

MCBRIDE ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 24-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 24-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Status of Claims***

Claim 44 has been cancelled in the present amendment.

Claims 24-43 (not 44 as stated in the REMARKS, INTRODUCTION section) are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112, first paragraph***

Claims 24-40 and 42-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action.

Applicants rely on MPEP section 2163 as providing guidelines as to the analysis of compliance with the written description requirement. Applicants argue that the guidelines provide that "generally there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement". And, that information well known in the art need not be described in detail in the specification. Applicants'

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arguments are confusing. The specification or applicants' argument does not specify what is well known in the art that need not be described in detail. Neither the prior art (see the newly submitted prior art below) nor the instant disclosure provides a detail description or information in relation to the treatment of a specific tumor, let alone, treatment of any kind or type of tumor(s). If an applicant choose to rely upon general knowledge in the art to render his disclosure enabling, the applicant must show that anyone skilled in the art would have actually possessed the knowledge, In re Lange (CCPA 1981) 644 F2d 856, 209 USPQ 288, or would reasonably be expected to check the source which applicant relies upon to complete his disclosure and would be able to locate the information with no more than reasonable intelligence. There is no explicit description in the specification as to the method of treating any type of tumor. Claims drawn to the use of known chemical compounds must have a corresponding written description only so specific as to lead one to that class of compounds. In re Herschler (CCPA 1979) 200 USPQ 711. Applicant can rely upon prior art which would enable one skilled in the art to glean therefrom the necessary information to render the specification enabling with respect to the first paragraph of 35 USC 112 but the burden is on applicant to point out precisely where

enablement lies in such disclosure. In re Albrecht II (CCPA 1975 ) 185 USPQ 590. However, not everything which may be cited as prior art to preclude the grant of a patent can be equated with common knowledge for the purposes of meeting the enablement requirement of 112.

Applicants direct the examiner's attention to page 15, lines 26-31 of the specification. The cited section is alleged to show possession of the claimed method of treating a tumor with the claimed radiolabeled peptides. A review of the section reveals nothing more than a generalized statement as to the peptide's ability to treat a tumor when administered to a host. Other than this general statement, there is nothing to show that any type of tumor, let alone, all tumors have actually been treated by the claimed method utilizing the claimed peptide. Applicants submit three new journals [de Jong, Lewis(Exhibits B and C)] to show that at the time the application was filed, the level of skill in the art to which the invention pertains was such that it is not necessary for applicants to include a great deal of detail in the specification to demonstrate that they were in possession of the invention.

De Jong is described to demonstrate that In-labeled somatostatin (hereinafter, SMS) analogs showed high and specific binding in vitro to somatostatin receptors in mouse pituitary

tumor cell membranes and that the different compound analogs showed specific internalization in rat pancreatic tumor cells. In addition, de Jong is described to show that the results translated to in vivo modes by biodistribution studies. In response, as correctly stated by applicants de Jong show the binding properties of SMS in vivo and in vitro. There is nothing in de Jong that correlates said binding to a treatment method for the single tumor, pancreatic, let alone for any type of tumor. Further, as recognized by applicants, the analogs described by de Jong are "..... promising for scintigraphy and radionuclide therapy of [SMS] receptor-positive tumors in humans." (Emphasis added).

Lewis (Exhibit B) basically discloses the same teaching as de Jong. Lewis (Exhibit C), like the other two references, merely shows uptake of the SMS analogs and states that the "greater tumor retention of [CU TETA Y3-TATE] justifies the selection of this agent for future PET imaging and targeted radiotherapy studies." (Emphasis ours).

Thus, at the time of applicants' invention, the extent to which the analogs have been used are only in the diagnosis of specific tumor. Treatment of even a specific tumor looks simply promising, still very much under investigative studies as shown by the three newly submitted prior art.

***Claim Rejections - 35 USC § 112***

Claims 24-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action as they appear in the following paragraphs:

A). It is argued that there is no provision in the MPEP or U.S. code that would preclude applicants from claiming a method of using the claimed radiolabeled peptide to treat tumors, where the radiolabeled peptides are characterized by the way they are made.

The general rule is that a product claim violates 35 USC 112, second paragraph, if structure is described by a process of making rather than in structural terms and the structure is capable of description in structural terms. In re Johnson, 157 USPQ 620, 623 (CCPA 1968).

B). The rejection of the claim under this paragraph is withdrawn in view of the amendment to claim 24.

C). Applicants reject the examiner's suggestion of specifying the number of carbon atoms present in the term lower and argue that the specification, page 11, lines 7-23 describes

the carbon atoms. A review of the relevant citation shows that the specification does not limit the carbon atoms recited therein. As stated in the last Office action, the term is given different definitions in the art as evident from the disclosure non-limiting numbers. Likewise, applicants argue that the substituents are described in the specification, *ibid*. However, applicants provide merely examples "such as cyclohexylmethyl." The phrase "such as" is indefinite. See MPEP § 2173.05(d).

D). Applicants argue that the skilled artisan would know, for example, when R1, R2, R3 are anything but "a protecting group that can be removed under the conditions of peptide synthesis," then the peptide is unprotected. It is not the language that is at issue herein. Rather, the conditions or method step of removing protecting group if present, when no process step in the synthesis and/or reagents or other contributing conditions necessary to remove said protecting group are recited therein. See *In re Johnson* above with respect to applicants' further arguments as to the method of using and making being claimed in a single claim.

E). See arguments under D). above.

F). The rejection of the claim is withdrawn in view of the cancellation of claim 44.

G). The rejection of the claim is withdrawn in view of amendment to claim 41.

**Conclusion**

*No claim is allowed.*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**REASSIGNMENT OF LOCATION**

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1639.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D.

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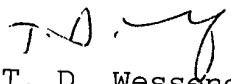
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Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw

January 12, 2003